B|BRAUN

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11JUN2024

URGENT MEDICAL DEVICE CORRECTION

ELECTRIC INFUSION PUMP ADMINISTRATION SET, SINGLE-USE-INFUSOMAT® and OUTLOOK® IV ADMINISTRATION SET

Backcheck Valve Malfunction

Dear Valued Customer:

The purpose of this letter is to inform you that B. Braun Medical Inc. (BBMI) is issuing a voluntary Urgent Medical Device Correction for ELECTRIC INFUSION PUMP ADMINISTRATION SET, SINGLE-USE-INFUSOMAT® and OUTLOOK® IV ADMINISTRATION SET due to the potential for the backcheck valve to malfunction, resulting in backflow of medication from secondary (piggyback) IV containers into primary IV containers and the inability to prime.

Affected Products:

The following products manufactured since August 05, 2023 are affected by this medical device correction:

Product Code	Product Description	GTIN-Primary Device ID	Region Distributed
354212	OUTLOOK IV SET 15DROP W/2 CARESITE	04046964293832	United States & Canada
354213	OUTLOOK IV SET 15DROP W/3 CARESITE	04046964182211	United States & Canada
362032	UNIV.15DROP PUMP SET W/3 SAFELINE LL	04046964182556	United States & Canada
362033	UNIV. 15 DR PUMP SET, 1.2 FIL, 2 CRSITE	04046964837821	United States
362034	60DROP METRISET PUMP SET, 3 SAFELINE	04046964182570	United States & Canada
362050	UNIV. 15 DROP PUMP SET W/ 0.2 FILTER	04046964182655	United States
362420	SPACE PUMP SET 15 DROP W/2 SAFEDAY	04046955592715	United States
362431	UNIV. 15 DROP PUMP SET W/ 3 ULTRASITE LL	04046964294013	United States
362432	SPACE PUMP IV SET, 120 IN.	04046964182679	United States
363010	60 DROP METRISET PUMP SET,3 SFLINE ASV	04046964294174	United States
363030	UNIV. 15 DROP PUMP SET W/3 SAFELINE, ASV	04046964294259	United States
363230	UNIV. 15 DROP PUMP SET, 3 ULTRASITE, ASV	04046964294495	United States & Canada
363420	SPACE PUMP IV SET, 2 CARESITES, ASV	04046964294594	United States & Canada
363421	UNIV. 15 DROP PUMP SET, 2 CARESITE, ASV	04046964294617	United States & Canada
363422	60DROP METRISET PUMP, 3 CARESITES, ASV	04046964294631	United States & Canada
363423	UNIV. 60 DROP PUMP SET, 2 CARESITES, ASV	04046964294655	United States & Canada
363424	UNIV. 15 DR PUMP SET, 1.2FIL, 2CRSTE ASV	04046964837906	United States & Canada

corrective actions are in place and the interim measures can be stopped. At this time, we anticipate that corrected sets may become available Q4 2024, but more definitive information will be provided in our follow-up notice.

Interim Measures for Users:

1. Until further notice, when administering secondary medications via piggyback please clamp the primary line above the upper Y site using the available slide clamp on the pump administration set. This will require unclamping of the primary line after delivery of the secondary medication. The instructions for this differ depending on the type of pump and software as outlined below:
    a. Attachment 1 provides workflow recommendations for Infusomat® Space Pumps with "U" software versions.
    b. Attachment 2 provides workflow recommendations for Infusomat® Space Pumps with "G" software versions and "L" (Canada only) software versions.
    c. Attachment 3 provides workflow recommendations for Outlook® ES Pumps.

    Note: This does not change workflows for rates of infusion greater than 300 mL/hr for Infusomat Pump Administration Sets and 125 mL/hr with Outlook Pump Administration sets where clamping of the primary infusion line is always required per the product IFU to prevent concurrent flow.
2. Inform all users and post the applicable attachment(s) in care areas where secondary infusions may be administered and where pump administration sets may be stored until further notice. B. Braun will provide additional notification when users may resume their normal secondary administration process without the need for the modified workflow.
3. Consider priming all pump administration sets with normal saline or other standard solutions prior to priming with expensive medications to avoid loss of expensive medications or occupational exposure to hazardous medications in the event that the pump administration set is unable to be primed. If difficulty priming is encountered obtain a replacement device and file a customer complaint with B. Braun. Adverse reactions or quality problems experienced with the products may be reported to BBMI's Postmarket Surveillance Department by calling 1-833-425-1464.

Actions Required by B. Braun Medical Inc. (BBMI) Customer/User:

1. Review this notice in its entirety.
    - Ensure that all users in your organization of the above-mentioned product, and other concerned personnel are informed about this voluntary correction and ensure that suitable interim measures are applied as described above. Present information to impacted clinicians at staff meetings, where appropriate.
    - Post this notification where the affected products are stored, where secondary infusions may be administered and in break rooms.
    - If you are a distributor and have further distributed the product, please forward this notice to your consignees.
    - The correction is to be extended to the hospital/healthcare facility level.
2. Return the completed "Urgent Medical Device Correction Acknowledgement Form" to B. Braun Medical Inc. Quality Assurance department by faxing the form to (610) 849-1197 or e-mail to recalls@bbraunusa.com within two (2) weeks of receipt, even if the total inventory in your possession is zero (0).

Adverse Reactions or Quality Problems:

Adverse reactions or quality problems experienced with this product, or questions about this correction may be reported to BBMI's Postmarket Surveillance Department by calling 1-833-425-1464.

In the United States:
Adverse Reactions or quality problems in the United Sates may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online[1]
- Regular Mail or Fax: Download form[2] or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

In Canada:
Adverse Reactions or quality problems in Canada may also be reported to Health Canada Online, via URL:

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ATTACHMENT 1

SECONDARY ADMINISTRATION PROCESS INFUSOMAT SPACE® SOFTWARE U

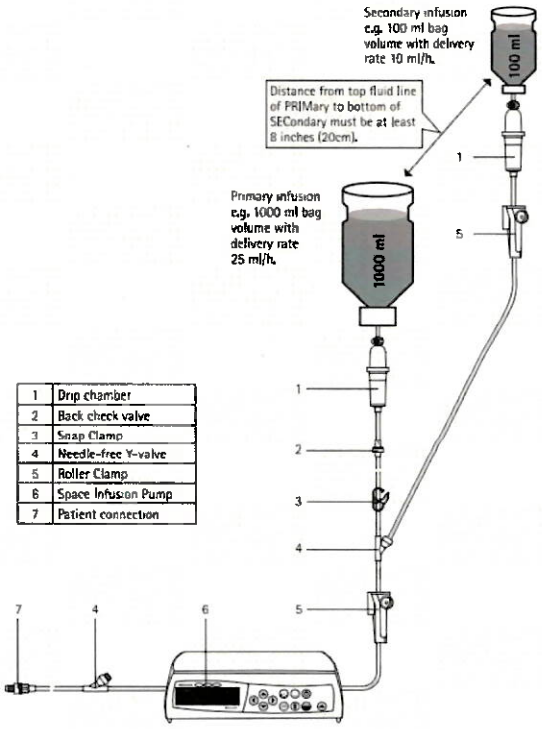
PURPOSE:

To provide workflow recommendations for clamping of the primary infusion line when administering secondary medications.

APPLICABILITY:

These recommendations apply only for pump administration sets used within Infusomat® Space Pumps with Software "U" versions. The software version of the Infusomat Space Pump can be verified by accessing the pump "Options" -> "Status" menu. Menus are accessed from the Home screen using the arrow keys. Press key while pump is running to access the Home screen. Software "U" versions begin with the prefix "X86U" (Example: X86U030017).

Note: Primary infusions with no secondaries connected can continue to be infused without impact. Refer to product IFU.

Step	Instruction
1	Close roller clamp. Fully spike secondary container. Hang fluid container. Gently squeeze and release drip chamber of secondary line until approximately half full. *NOTE: Vent cap should remain in the closed position unless infusing from a solid stopper glass bottle.* *NOTE: SECondary infusion should not be used for critical infusions.*
2	Prime secondary set by slowly opening roller clamp and allow fluid to fill tubing. Close roller clamp. Ensure air is expelled. Repeat prime if necessary.
3	Lower primary container such that the top fluid line of the primary is at least 8 in. (20 cm) below the bottom of the secondary IV container. 
4	Swab upper access port on primary set and attach secondary set to the primary set.

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ATTACHMENT 2

SECONDARY ADMINISTRATION PROCESS INFUSOMAT SPACE® SOFTWARE G & L

PURPOSE:

To provide workflow recommendations for clamping of the primary infusion line when administering secondary medications.

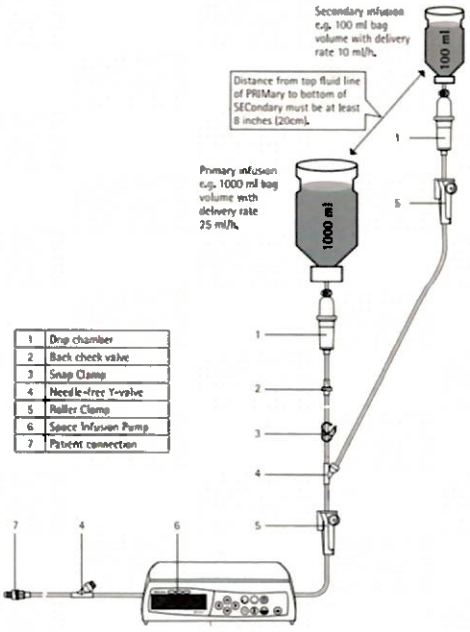
APPLICABILITY:

These recommendations apply only for pump administration sets used within Infusomat® Space Pumps with Software "G" or "L" versions. The software version of the Infusomat Space Pump can be verified by accessing the pump "Options" -> "Status" menu.

Menus are accessed from the Home screen using the arrow keys. Press key while pump is running to access the Home screen. Software "G" versions begin with the prefix "X86G" (Example: X86G030102). Software "L" versions begin with the prefix "X86L" (Example: X86L032101). Note that Software L is utilized only in Canada.

Note: Primary infusions with no secondaries connected can continue to be infused without impact. Refer to product Instructions for Use (IFU).

Step	Instruction
1	Close roller clamp. Fully spike secondary container. Hang fluid container. Gently squeeze and release drip chamber of secondary line until approximately half full. *NOTE: Vent cap should remain in the closed position unless infusing from a solid stopper glass bottle.* *NOTE: SECondary infusion should not be used for critical infusions.*
2	Prime secondary set by slowly opening roller clamp and allow fluid to fill tubing. Close roller clamp. Ensure air is expelled. Repeat prime if necessary.
3	Lower primary container such that the top fluid line of the primary is at least 8 in. (20 cm) below the bottom of the secondary IV container.



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ATTACHMENT 3

SECONDARY ADMINISTRATION PROCESS OUTLOOK ES®

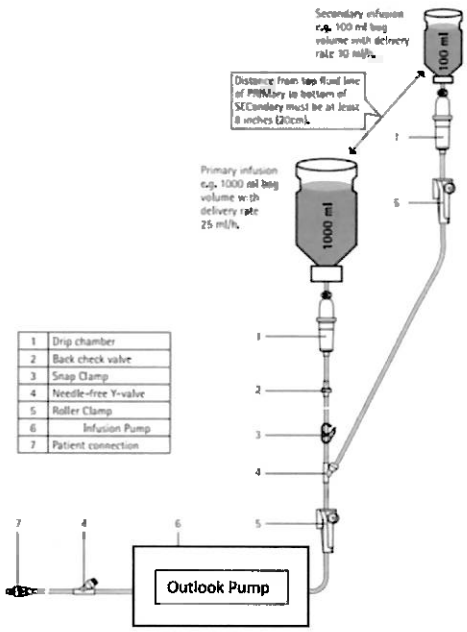
PURPOSE:

To provide workflow recommendations for clamping of the primary infusion line when administering secondary medications.

APPLICABILITY:

These recommendations apply only for pump administration sets used within Outlook ES® pumps.

Note: Primary infusions with no secondaries connected can continue to be infused without impact. Refer to product Instructions for Use (IFU).

Step	Instruction	Picture
1	Close roller clamp. Fully spike secondary container. Hang fluid container. Gently squeeze and release drip chamber of secondary line until approximately half full. *NOTE: Vent cap should remain in the closed position unless infusing from a solid stopper glass bottle.* *NOTE: SECondary infusion should not be used for critical infusions.*	
2	Prime secondary set by slowly opening roller clamp and allow fluid to fill tubing. Close roller clamp. Ensure air is expelled. Repeat prime if necessary.	
3	Lower primary container such that the top fluid line of the primary is at least 8 in. (20 cm) below the bottom of the secondary IV container.	
4	Swab upper access port on primary set and attach secondary set to the primary set.	

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Urgent Medical Device Correction Acknowledgement Form

ELECTRIC INFUSION PUMP ADMINISTRATION SET, SINGLE-USE-INFUSOMAT® and OUTLOOK® IV ADMINISTRATION SET
Backcheck Valve Malfunction

Please complete and return this form by one of the below options:
Fax: (610) 849-1197 or **Email** recalls@bbraunusa.com

Bound Tree Medical
1605 Zeager Rd
ELIZABETHTOWN, PA 17022
0020801686

Completing and returning this form indicates you have read and understand the Urgent Medical Device Correction Notification.

Distributors ONLY:
☐ ***DISTRIBUTORS ONLY* - checking this box indicates you have forwarded this notice to your affected consignees.**

PLEASE FULLY COMPLETE APPLICABLE SECTIONS BELOW:

- **Distributors: Complete the Distributor Information on the left-hand side of the table below.**
- **End Customers: Complete the End Customer Information on the right-hand side of the table below.**

Distributor Information	End Customer Information
Distributor Name, if applicable: Bound Tree Medical	Facility Name:
Distributor Account #, if applicable: 0020801686	Account Number:
Distributor Address, if applicable: 1605 Zeager Rd, ELIZABETHTOWN, PA 17022	Address:
Signature of Person Completing Form:	Signature of Person Completing Form:
Printed Name:	Printed Name:
Telephone Number:	Telephone Number:
Fax Number:	Fax Number:
Date:	Date:
E-Mail:	E-Mail: